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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/397,110	09/16/99	MOORE	N

EXAMINER	
PORTNER, V	
ART UNIT	**PAPER NUMBER**
1645	6

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DATE MAILED: 09/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File Copy

Office Action Summary	Application No. 09/397,110	Applicant(s) Moore et al
	Examiner Portner	Art Unit 1645

-- The MAILING DATE of this communication appears n the cover sheet with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 30, 2001* .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-32* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Claims 1-30 and 31-32 are pending.

Claims 31-32 were newly submitted.

Claims 20, 30, 31 and 32 have been amended to depend indirectly from claim 10.

Election/Restriction

1. Applicant's election of claim 10 with traverse of in Paper No. 5, dated January 30, 2001 is acknowledged. The traversal is on the ground(s) that the "distinctness among the various groupings set forth in the office action is highly speculative and rests on unjustified and insupportable assumptions".

These arguments have been fully considered but are not found to be persuasive for the reasons below.

First, the classification system has no statutory recognition whether inventions are independent and distinct. For example, each class and subclass is comprised of numerous completely independent and distinct inventions.

Second, MPEP 803 states that restriction is proper between patentably distinct inventions where the inventions are (1)independent or distinct as claimed and (2) a serious search and examination burden is placed on the examiner if restriction is not required.

The term "distinct" is defined to mean that two or more subjects as disclosed are related, for example, as product and method of use, but are capable of separate manufacture, use or sale

as claimed, and are patentable over each other (see MPEP 802.1). In the instant situation, the inventions of Groups I-VII are drawn to distinct inventions which are related as separate products capable of separate functions, for example: C-polysaccharide and antibodies are structurally and functionally different. Restrictions between the inventions is deemed to be proper for the reason previously set forth.

In regard to burden of search and examination, MPEP 803 states that a burden can be shown if the examiner shows either separate classification, different field of search or separate status in the art. In the instant case a burden has been established in showing that the inventions of Groups I-VII are classified separately necessitating different searches of issued US Patents and the structures defined by the device of Group VI (requires a window, a label, antigen, antibodies, a bibulous material and zones in a specific configuration) which are not required for carrying out the method of Group V (no specific configuration is required, other than the assay being carried in a immunochromatographic assay process). However, classification of subject matter is merely one indication of the burdensome nature of search. The literature search, particularly relevant in this art, is not co-extensive, because for example antibodies differ from antigens, and reagents needed for purifying an antigen are not the same combination of reagents for detecting an antigen is a sample. Additionally, it is submitted that the inventions of Groups I-VII have acquired a separate status in the art. Clearly different searches and issues are involved in the examination of each Group. For these reasons the restriction requirement is deemed to be proper and is therefore made Final.

While Applicant did elect claim 10, and all claims that directly or indirectly depend from claim 10, and submitted an amendment which defined additional claims 1, 3-6 and 11-30 to depend from claim 10, the election made by Applicant's was not fully responsive in light of election included multiple groups that had been defined as independent and distinct inventions.

In light of response being a bonafide attempt, the following Election/Restriction is being sent out once again, and Applicant is required to elect a single Group/invention though it may be with traverse.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1,3-6 , drawn to methods of obtaining a C-polysaccharide antigen using acid/base neutralization methods of extraction, classified in class 536, subclass 124.

II. Claims 2, drawn to C-polysaccharide antigen, classified in class 536 , subclass 123.1.

III. Claims 7 is, drawn to methods of affinity purifying antibodies, classified in class 530, subclass 389.5.

IV. Claim 8, drawn to antibodies specific to C-polysaccharide, classified in class 530, subclass 388.4.

V. Claims 10-19 are, drawn to methods of assaying for the presence of S.pneumoniae or C-polysaccharide using extracted bacterial antigen to affinity purify antibodies

and assaying by any immunoassay method of detection, classified in class 435, subclass 7.34.

VI. Claims 20-30, 31-32 drawn to an assay device and method of using the assay device to detect the presence of S.pneumoniae or C-polysaccharide cell wall antigen, classified in class 436, subclass 535.

VII. Claim 9 is, drawn to a chromatographic column to which is immobilized C-polysaccharide, classified in class 422, subclass 70.

3. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case that the product as claimed can be made by another and materially different process, wherein the polysaccharide has been purified by methods that result in less than 10% protein by methods known in the art (see Havas et al, 1984, reference being made of record).

4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different

process of using that product, wherein the polysaccharide antigen is useful in the induction of antibodies, in methods of detecting diagnostic antibodies for diagnosis of infection, in the production process of producing monoclonal antibodies and in the production of molecular image polymers.

5. Inventions III and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case that the product as claimed can be made by another and materially different process, wherein the antibodies may be either monoclonal or polyclonal antibodies that are monospecific to C-polysaccharide antigen that contains less than 10% protein, and monoclonal antibodies would be monospecific to C-polysaccharide without the need for affinity purification.

Monoclonal antibodies to C-polysaccharide are monospecific and would not contain antibodies to any proteins. Gillespie et al (1994) produced a monoclonal antibody to S.pneumoniae C-polysaccharide which is a product that was produced by a materially different process and would meet the claimed invention of Group 8.

6. Inventions IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product, wherein the antibodies are useful in the affinity purification of antigen, in methods of detecting infection, in methods of producing anti-idiotypic antibodies for therapy and in the production of molecular image polymers.

7. Inventions VI and V are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because:

a. The combination of Group VI does not require the use of reagents for extraction of a culture of S.pneumoniae as required in Group V.

b. The subcombination defined by Group V has separate utility such as using the antibodies to detect infection without the use of a chromatographic device with zones. Immuno-precipitation assays, enzyme-linked immunosorbant assays, as well as homogenous nephelometric assays may be used. The method of detection may be any method and the immunochromatographic methods recited in dependent claims 17-19 do not require the structural components of the device defined in Group VI.

8. Inventions VII and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the

product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of Group VII can be used to identify and purify receptors from mammalian cell surfaces based upon bacterial polysaccharide affinity binding (see Sundberg-Kovamees et al abstract (1996) being made of record), as well as can be used to purify antibodies.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, the search required for each of Groups I-IV differs and have been recognized as divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (703)308-7543. The examiner can normally be reached on Monday through Friday from 7:30 AM to 5:00 PM except for the first Friday of each two week period.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this group is (703) 308-4242.

The Group and/or Art Unit location of your application in the PTO will be Group Art Unit 1645. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to this Art Unit.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Vgp
September 18, 2001

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1